AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-17 (Canceled)

18. (Withdrawn) A method of diagnosing Alzheimer's disease in a human patient suspected of having Alzheimer's disease, wherein said human does not exhibit symptoms of multiple sclerosis or menginoencephalitis, said method comprising obtaining a cerebrospinal fluid sample from said patient, determining whether said cerebral spinal fluid sample contains Chlamydia pneumoniae, wherein the presence of Chlamydia pneumoniae in said sample is an indication that said patient has Alzheimer's disease.

19. (Withdrawn) A method of diagnosing Alzheimer's disease in a human patient suspected of having Alzheimer's disease, wherein said human does not exhibit symptoms of multiple sclerosis or menginoencephalitis, said method comprising measuring the serum anti-Chlamydia pneumoniae antibody titer in a patient suspected of having Alzheimer's disease and comparing the serum anti-Chlamydia pneumoniae antibody titer in said patient with the mean serum anti-Chlamydia pneumoniae antibody titer in a population of control patients, wherein a higher serum anti-Chlamydia pneumoniae antibody titer in said patient compared with said mean serum anti-Chlamydia pneumoniae antibody titer is an indication that said patient has Alzheimer's disease.

20. (Withdrawn) A method of diagnosing Alzheimer's disease in a human patient, said method comprising administering an anti-SAF antibody to said human and determining whether said anti-SAF antibody binds to central nervous system tissue in said human, wherein binding of anti-SAF antibody to central nervous tissue in said human is an indication that said human has Alzheimer's disease.

21. (Withdrawn) The method of claim 20, wherein said anti-SAF antibody is administered to said human intrathecally.

22. (Withdrawn) The method of claim 21, wherein said antibody is labeled with a detectable label and wherein binding of said antibody is assessed by detecting said label bound to said tissue.

23. (Withdrawn) An anti-SAF antibody molecule.

24. (Withdrawn) The anti-SAF antibody molecule of claim 25, wherein said antibody is selected from the group consisting of a monoclonal antibody and a synthetic antibody.

25. (Withdrawn) An ELISA kit comprising an anti-SAF antibody and an instructional material.

26. (Withdrawn) A method of diagnosing Alzheimer's disease in a human patient, said method comprising detecting evidence of the presence of C. pneumoniae in an intranasal sample obtained from said patient, wherein when the presence of C. pneumoniae in said sample is an indication that said patient has Alzheimer's disease.

27. (Withdrawn) A method of identifying a candidate compound for treatment of Alzheimer's disease comprising incubating cells infected with Chlamydia pneumoniae in the presence or absence of a test compound and measuring the level of replication of said Chlamydia pneumoniae in said cells, wherein a lower level of replication of said Chlamydia pneumoniae in the presence of said test compound compared with the level of replication of said Chlamydia pneumoniae in the absence of said test compound, is an indication that said test compound is a candidate compound for treatment of Alzheimer's disease.

28. (Withdrawn) The method of claim 27, wherein said cells are selected from the group consisting of monocytes/microglia, macrophages, oligodendroglia, astroglial and neuronal cells.

29. (Withdrawn) A neuronal cell infected with Chlamydia pneumoniae.

30. (Withdrawn) A plurality of neuronal cells infected with Chlamydia pneumoniae.

31. (Previously Presented) A method of treating Alzheimer's disease in a living being comprising administering to the living being a therapeutic amount of an anti-microbial agent.

32. (Canceled)

33. (Previously Presented) The method of claim 31 wherein the anti-microbial agent is selected from the group consisting of ciproflaxacin, oflaxacin, sulfamethoxadole, trimethoprim, doxycycline, minocycline, oxytetracycline, tetracycline, azithromycin, clarithromycin, dirithromycin, erythromycin and troleandomycin.

34. (Previously Presented) A method of treating Alzheimer's disease in a living being comprising administering to the living being a therapeutic amount of an anti-microbial agent and an anti-inflammatory agent.

35. (Canceled)

36. (Currently amended) The method of claim [[36]] 34 wherein the anti-microbial agent is selected from the group consisting of ciproflaxacin, oflaxacin, sulfamethoxadole, trimethoprim, doxycycline, minocycline, oxytetracycline, tetracycline, azithromycin, clarithromycin, dirithromycin, erythromycin and troleandomycin.

37. (Previously Presented) The method of claim 34 wherein the anti-inflammatory agent is a non-steroidal anti-inflammatory agent.

38. (Previously Presented) The method of claim 34 wherein the anti-inflammatory agent is selected from the group consisting of ibuprofen, phenylbutazone, indomethacin, sulindac, diclofenac, proxicam, naproxen, ketoprofen, pirprofen, flurbiprofen, tiaprofenic acid, tolfenamic acid and a COX-2 inhibitor.

39. (New) The method of Claim 31 wherein the anti-microbial agent is doxycycline.

40. (New) The method of Claim 31 wherein the antimicrobial agent is a macrolide.

41. (New) The method of Claim 40 wherein the macrolide is selected from the group consisting of azithromycin, clarithromycin, dirithromycin, erythromycin and troleandomycin.

42. (New) The method of Claim 41 wherein the macrolide is azithromycin.

43. (New) The method of Claim 31 wherein the antimicrobial agent is a fluoroquinolone.

44. (New) The method of Claim 43 wherein the fluoroquinolone is selected from the group consisting of Ciprofoxacin and Ofloxacin.

45. (New) The method of Claim 31 wherein the antimicrobial agent is a sulfonamide.

46. (New) The method of Claim 31 wherein the antimicrobial agent comprises both sulfamethoxazole and trimethoprim.

47. (New) The method of Claim 31 wherein the antimicrobial agent is Ciprofoxacin.

48. (New) The method of Claim 31 wherein the antimicrobial agent is Ofloxacin.

49. (New) The method of Claim 31 wherein the antimicrobial agent has an antichlamydia activity equal to or greater than that of azithromycin.

50. (New) The method of Claim 49 wherein the antimicrobial agent is a macrolide.

51. (New) The method of Claim 34 wherein the anti-microbial agent is doxycycline.

52. (New) The method of Claim 34 wherein the antimicrobial agent is a macrolide.

53. (New) The method of Claim 52 wherein the macrolide is selected from the group consisting of azithromycin, clarithromycin, dirithromycin, erythromycin and troleandomycin.

54. (New) The method of Claim 53 wherein the macrolide is azithromycin.

55. (New) The method of Claim 34 wherein the antimicrobial agent is a fluoroquinolone.

56. (New) The method of Claim 55 wherein the fluoroquinolone is selected from the group consisting of Ciprofoxacin and Ofloxacin.

57. (New) The method of Claim 34 wherein the antimicrobial agent is a sulfonamide.

58. (New) The method of Claim 34 wherein the antimicrobial agent comprises both sulfamethoxazole and trimethoprim.

59. (New) The method of Claim 34 wherein the antimicrobial agent is Ciprofoxacin.

60. (New) The method of Claim 34 wherein the antimicrobial agent is Ofloxacin.

61. (New) The method of Claim 34 wherein the antimicrobial agent has an antichlamydia activity equal to or greater than that of azithromycin.

62. (New) The method of Claim 61 wherein the antimicrobial agent is a macrolide.

REMARKS/ARGUMENTS

By this Amendment, claim 36 has been amended. Dependent Claims 39-62 have been added. Claims 31, 33-34 and 36-62 are pending.

Support for New Claims

Support for claims referring to doxycycline can be found in the application at page 22, lines 4-10 and 18-20.

Support for claims referring to azithromycin or other macrolide can be found at page 22, lines 11-20.

Support for claims referring to a fluoroquinolone can be found at page 21, lines 15-22.

Support for claims referring to a sulfonamide can be found at page 21, lines 23-27.

Support for claims referring to both sulfamethoxazole and trimethoprim can be found at page 22, line 1-3.

Support for claims referring to Ciprofoxacin or Oflaxacin is found at page 6, lines 4 through 7 and lines 23 through 26.

Rejection of Claims under 35 U.S.C. 112, second paragraph

The Examiner states that claim 36 is rejected under 35 U.S.C. 112, second paragraph, as having improper dependency. Accordingly, Applicants have amended claim 36 to correct the dependency.

Rejection of claims under 35 U.S.C. §102(a) as anticipated by Mitchell et al

The Examiner has rejected all claims pending at the time of the Office Action in view of Mitchell at al' ("Mitchell"). The earliest application for which Mitchell claimed priority was provisional application serial number 60/023,921 filed on August 14, 1996. The Examiner states that the effective date of the Mitchell patent is August 14, 1996. However, provisional application serial number 60/023,921, makes no reference to Alzheimer's Disease. The next earliest applications for which Mitchell claimed priority were filed on May 7, 1997. Applicants submitted, on April 20, 2005, a Declaration of Dr. Brian Balin as proof of Applicants' conception predating May 6, 1997. Therefore the rejection based on Mitchell is traversed.

Rejection of claims under 35 U.S.C. §103(a) as obvious over Mitchell

The Examiner has rejected all claims pending at the time of the Office Action in view of Mitchell. This rejection is traversed on the same grounds as the rejection under 35 U.S.C. §102(a) discussed above.

Rejection of claims 31 and 33 under 35 U.S.C. §102(b) as being anticipated by McClachlan

As a basis for this rejection, the Examiner cites a particular passage in McClachlan referring to medicaments "which are recognized to have beneficial effects in Alzheimer's disease, such as e.g., tetracycline, sodium fluoride, calcium lactate-gluconate or other calcium salts, vitamin D3 and/or ascorbic acid."

The issue is whether the use of tetracycline to treat Alzheimer's disease would have been obvious to a person of ordinary skill in the art in view of the McClachlan disclosure.

A pertinent fact is that the Examiner was able to find only that single reference to the benefits of tetracycline on Alzheimer's disease. The reference is devoid of data on the effect of tetracycline and does not cite a primary reference for the basis of the statement. (A primary reference would be one in which the data on tetracycline would have been presented.) Given the

importance of the disease, and given McClachlan's statement that tetracycline's beneficial effect was recognized, it would be expected that it would not be difficult to find such a primary reference, if it in fact existed. However, no such reference has been cited. The foregoing considerations, taken in their entirety, suggest that a person of ordinary skill in the art would not have considered tetracycline to be beneficial for Alzheimer's disease. The attached "Declaration of Dr. Brian J. Balin Under 37 CFR 1.132" (copy of original is attached) further supports the latter view. It states that:

1) During the period December 21, 1981 through December 6, 1983, tetracycline was not recognized to have beneficial effects in Alzheimer's Disease; and

2) During the period December 7, 1983 until the dates of the inventions by the applicants claimed in the present application serial number 09/227,749, tetracycline was not recognized to have beneficial effects in Alzheimer's Disease.

December 21, 1981 and December 6, 1983, are the filing and issue dates, respectively, of the McClachlan patent.

In view of the foregoing, the rejection based on McClachlan is traversed.

Rejection of claims under 35 U.S.C. §103(a) as being unpatentable over McClachlan in combination with either Elsberry et al or Xiatao et al

This rejection is traversed on the same grounds as the rejection under §102(b).

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.

November 9, 2005

By
Allan H. Fried
Registration No. 31,253
Customer No. 03000
(215) 567-2010
Attorneys for Applicants

Please charge or credit our Account No. 03-0075 as necessary to effect entry and/or ensure consideration of this submission.